K094002

5. 510(k) Summary

Contact:	Henry Klyce President, CEO Spartek Medical, Inc.
Date Prepared:	May 6, 2010
Device Trade Name:	Spartek™ Variable Angle Pedicle Screw Posterior Fusion System
Manufacturer:	Spartek Medical, Inc. 1100 Marina Village Pkwy, Suite 103 Alameda, CA 94501
Common Name:	Pedicle screw spinal system
Classification:	21 CFR §888.3070, Class III
Product Codes:	NKB, MNH, MNI

MAY - 7 2010

Indications For Use:
The Spartek™ Variable Angle Pedicle Screw Posterior Fusion System is intended for immobilization and stabilization of the thoracic, lumbar, and sacral spine in skeletally mature patients as an adjunct to fusion with autogenous bone graft for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

Device Description:
The Spartek™ Variable Angle Pedicle Screw Posterior Fusion System is a single use device for mono- and multi-segmented stabilization of the lumbar and thoracic vertebrae to facilitate fusion, per the indications for use. The system consists of post and fixed head screws, washers, rods, set screws, and locking nuts.

Predicate Device(s):
The Spartek™ Variable Angle Pedicle Screw Posterior Fusion System was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and materials.

Performance Standards:
Testing performed indicates the Spartek™ Variable Angle Pedicle Screw Posterior Fusion System is substantially equivalent to predicate devices as demonstrated through static compression bending, static torsion, and dynamic compression bending as described in ASTM F1717, and other special controls.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Spartek Medical, Inc.
% Mr. Henry A. Klyce
President, CEO
1100 Marina Village Parkway
Suite 103
Alameda, California 94501

MAY - 7 2010

Re: K094002
Trade/Device Name: Spartek™ Variable Angle Pedicle Screw Posterior Fusion System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI
Dated: April 21, 2010
Received: April 22, 2010

Dear Mr. Klyce:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K094002

Device Name: Spartek™ Variable Angle Posterior Fusion System

The Spartek™ Variable Angle Pedicle Screw Posterior Fusion System is intended for immobilization and stabilization of the thoracic, lumbar, and sacral spine in skeletally mature patients as an adjunct to fusion with autogenous bone graft for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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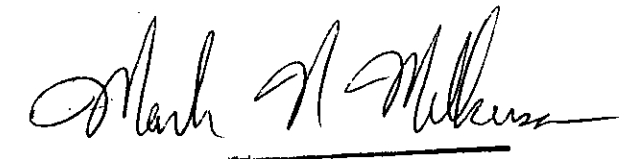
Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K094002